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Case Analysis of an Adverse Event Related to Treatments of Medical Devices According to ALARM Method

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Abstract

Introduction: The process of sterilization is complex and invasive procedures performed with insufficiently sterilized Medical Devices (MDs) have the potential risk to transmit infection. Therefore, it was crucial to discover sterilization problems and reporting Adverse Events (AEs) related to treatment of MDs. The objective of the present study was to analyze a case of AEs related to treatment of MDs according to Association of Litigation and Risk Management (ALARM) Method.

Methods: The study was carried out in Sahloul University Hospital (Tunisia). We studied all AEs related to the treatment of MDs over three years (June 2018 to June 2021). Data were collected using the AEs reporting form, by service quality referents, medical and paramedical health professionals. Unacceptable AE was analyzed using ALARM method.

Results: Only one AE was unacceptable risk having a criticality of 10: It occurred during the pre-disinfection step where the battery of a medical device was not removed in the operating room. These AEs was related to insufficient control before steam sterilization in both the operating room and the central sterilization unit. It was an unacceptable risk was analyzed according to ALARM method: Personal factors (training), teams and organizational factors (intra and inter unit communication) and task factors were contributed to this AE. We implemented corrective measures and their follow up in both central sterilization unit and operating rooms.

Conclusion: It was the first study describing reported AEs related to treatment of MDs by reporting system in our hospital. Underreporting of AEs and feedback were the main limitations of this reporting system. The notification of incidents must take place with the support of trained and convinced operating rooms personnel.

Keywords: Sterilization; Medical device; Adverse event; ALARM method

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Introduction

Medical Devices (MDs) are commonly used in healthcare for diagnosis, prevention, treatment and monitoring of diseases and injuries [1,2].

Throughout the world, sterilization of reusable MDs is a daily requirement. It's comprise a complex process [3]. It's intended for reprocessing are, in most cases, made of robust materials that can withstand during sterilization process [4]. Over the past fifteen years, the hospital sterilization unit has been marked by a series of major organizational and technical developments. The regulatory and normative environment has evolved considerably to guarantee operated patients a secure use of reusable MDs [5]. Despite their benefit, these MDs must be adequately sterilized prior to reuse or they may be a source of many Adverse Events (AEs). If patients use incompletely sterilized MD, or there is a shortage of packs, it may cause delays in operations or nosocomial infections, which will directly compromise the safety of the patients, operations and even the reputation of the hospital [4,6].

The World Health Organization has also advocated "Safe Surgery, Save Lives" calling on all countries in the world to make surgical safety a key medical quality policy [6]. Therefore, detecting adverse medical device events and AEs related to treatment of MDs are crucial for patient safety.

		Severity				
		1	2	3	4	5
Frequency	1	1	2	3	4	5
	2	2	4	6	8	10
	3	3	6	9	12	15
	4	4	8	12	16	20
	5	5	10	15	20	25

Figure 1: Matrix of criticality.

Index	Criticality class or risk levels	Decisions and actions
C1	acceptable	No action is to be taken
C2	tolerable	We must organize a follow-up in terms of risk management
C3	unacceptable	We must refuse the situation and take measures to reduce the risks

Figure 2: Criticality class or risk levels.

AEs in complex systems, such as health care delivery and sterilization unit, are typically the result of multiple latent errors that predispose individuals in the system to, in turn, commit acute errors leading to AEs [2,3].

Despite the existence many patient safety studies, the majority are focused on the monitoring of adverse MDs events called "materiovigilance", while reporting AEs related to treatment of MDs is scarce [2,7,8].

As part of continuous quality improvement process in Sahloul University Hospital, in 2018, a voluntary AEs reporting system has been implemented. That's why; we propose to analyze a case of AEs related to treatment of MDs according to Association of Litigation and Risk Management (ALARM) Method.

Method and Materials

The case study was carried out in Sahloul University Hospital (Tunisia) over three years (June 2018 to June 2021). A voluntary adverse events reporting system had been implemented at the Sahloul University Hospital since 2018. In our study, we included all AEs related to the treatment of MDs. Operating linen and plastic material events were not included.

Data were collected using the AEs reporting form, by service quality referents, medical and paramedical health professionals.

Collected data included the reporting person, the characteristics of the AE (date, time, place), the AE concerned a person (patient, healthcare professionals, visitors, etc.) or a health product (a drug, a MD, a chemical or biological product, etc.), description of the AE, the possible causes of the AE as well as the immediate actions taken and proposed solutions, estimating AE severity and frequency. In our study, we were interested only to AEs related to the treatment of MDs.

An adverse event is commonly defined as an unintended injury that results in temporary or permanent disability, death, or prolonged hospital stay and is caused by healthcare management rather than by the patient's underlying disease process [9].

AEs related to the treatment of MDs: These are the AEs that occurred during the treatment steps for heat-resistant MDs, namely cleaning and pre disinfection, packaging of MDs steam sterilization, storage and delivery, control, traceability of MDs and organization.

Frequency was defined as exceptional when the event happens less than once a year, rare if 1 to 3 times a year, uncommon if at least once a quarter, frequent or common if at least once a month and very common if at least once a week.

The severity level was determined according to the consequences on the patient or the healthcare professional and impact on the organization (Table 1).

In the present study, we analyzed AEs related to treatment of MDs with the highest criticality. Indeed, when AEs related to treatment of MDs was reported; a member the AEs management committee codified and registered the reporting form. In fact, an order number was assigned to each AEs reported. A reception form in duplicate was completed and a copy was sent to the declaring person. Then, AEs management committee meet within 5 days of the occurrence of the AE where reported AE were ranked according to a criticality scale structured according to 3 levels of risk. According to ISO 31000 [4], the criticality was calculated according to the following formula:

C = Frequency × Severity. A decision matrix had been developed allowing the definition of risk levels according to the criticality class, which allowed us to establish the risk levels of the presented in Figure 1, 2.

Any unjustified AE will be rated as criticality 1 (Gravity 1, frequency 1) and closed, supplemented by an explanatory analysis report.

Any AE with real impact must be the subject of an in-depth analysis carried out on the basis of ALARM method. After chronological reconstruction of the AEs, the method explored the root causes and factors namely institutional contexts (Economic and regulatory context; national health service executive; clinical negligence scheme for trusts), organizational and managerial factors (Financial resources and constraints; organizational structure; policy; standards and goals; safety culture and priorities), work environment factors (Staffing levels and skills mix; workload and shift patterns; design, availability, and maintenance of equipment; administrative and managerial support), individual factors, team factors (Verbal communication; written communication; supervision and seeking

help) and patient factors (Knowledge and skills; competence; physical and mental health).

All the corrective actions proposed concerning the declared AE are recorded in the corrective action sheet. The implementation of the proposed actions is entrusted to the quality referent and the head of the department concerned.

In the present study, we analyzed AEs related to treatment of MDs with the highest criticality. Monitoring and evaluation of corrective actions was a mandatory step and was done using monitoring indicators.

Data analysis was performed using the SPSS statistical package (version 20.0, SPSS Inc, Chicago, IL, USA).

The results were presented as case analysis according to the ALARM. At first, we described the AE. Then we determined main causes, factors favoring the occurrence of these causes (Institutional context, organizational and managerial factors, work environment factors, individual (staff) factors, team factors task factors and patient factors). Finally, we determined corrective actions. Monitoring and evaluation of corrective actions was a mandatory step and was done using monitoring indicators.

Ethical considerations: This surveillance system was based on anonymity and confidentiality (the charter to encourage reporting).

Results

We analyzed AE related to treatment of MDs having a criticality of 10: It occurred during the pre-disinfection step where the battery of a micro air motor battery was not removed. These AEs was related to insufficient control before steam sterilization.

A Monday morning, February 25th, 2019, the orthopedic operating room reported an AE concerning a malfunction of a micro air motor that was used in the emergency operating room the day before. The investigation group was constituted by a member of the committee for the management of AEs attached to the Prevention and Security of Care Unit, those in charge of the CSU (doctor and unit supervisor) and staff from emergency and orthopedic operating rooms and CSU. Then, an investigation started by questioning, in turn, healthcare professionals directly or indirectly implicated in the incident, during several meetings.

During the previous night shift (February 24th), the emergency operating room team used their two micro air motors, and needed a third. They borrowed the one from the orthopedic operating room. In the afternoon, after its use, the micro air motor was sent to the CSU by a trainee instrumentalist, without removing the battery from the motor.

Received by the team of this unit, this motor was packaged before being placed in the autoclave by a worker, without checking for the presence of the battery. Arrived at the orthopedic operating room on Monday morning, a finding of a non-functional motor was made.

The main causes emerge from the study of the adverse effect were in number of two. The first cause was that in the emergency operating room, the trainee instrumentalist did not remove the battery from the micro air motor in pre-disinfection step and sent it directly to the sterilization unit. The second cause was at the sterilization unit; the worker cleaned and packaged the motor without having checked whether it still contained the battery.

The factors favoring the occurrence of the cause at the operating room were divided into personal factors (unqualified person, lack of seeking advice and collaboration), team factors (lack of supervision and framing), task factors (procedures and technical sheets of micro air motor were non-existent at the emergency operating room), work environment factors (heavy workload during weekend call and use of equipment was common between operating rooms) and organizational and managerial factors (responsibilities and tasks were poorly defined, there was a coordination failure between the emergency operating room and the central serialization unit, there was Insufficient financial availability).

The factors favoring the occurrence of the CSU cause were personal factors (The nurse at the CSU was late, the worker started packaging the MD on his own without waiting the nurse, lack of seeking advice and collaboration, lack of motivation), Team factors (lack of supervision during weekend shifts, lack of internal communication within the CSU team), task factors (procedures and technical sheets of micro air motor were non-existent at the CSU), Organizational factors (responsibilities and tasks were poorly defined, lack of communication between the two workstations, lack of organization within the CSU team, human resource management was inadequate).

The corrective measures and their follow up in both central sterilization unit and operating rooms were summarized in Table 2.

Discussion

The process of sterilization was complex and invasive procedures performed with insufficiently sterilized instruments had the potential risk to transmit infection, to delay or cancel surgery [3]. Therefore, it was crucial to discover sterilization problems and reporting AEs related to treatment of MDs. The objective of the present study was to determine the incidence of reporting AEs related to treatment of MDs

Table 1: Severity level of AEs.

Severity Levels	Patient /Health Professional	Organization
Minor	No effect on the moral and physical state of the patient. Nonstop work accident	No effect on the process, activity and security.
Moderate	Discomfort or slight discomfort transient without damage to health. Superficial involvement Feeling insecure Work stoppage <21 days	Effect does not undermine the operation of the process.
Serious	Health impact increasing the duration of hospitalization or re hospitalization. Work stoppage between 21 days and 90 days	Operation disrupted process: Unavailability of resources …
Critical	Worsening health status with reversible effect. Commitment of the vital prognosis. Work stoppage >90 days	Temporarily stopping the activity, partial closure. Questioning of the functioning of the process.
Catastrophic	Death, irreversible health effects	Prolonged stoppage of activity

Table 2: Corrective measures and follow-up of corrective measures.

Units	Corrective Measures	Follow-Up
CSU	Reminding note to check all motors sent to the CSU	Reminding note displayed
	Implementing checklist checking the micro air motor	Implemented checklist
	Training and awareness of CSU staff on the importance of checking the materials provided by other unit and	Sensitization was made by the supervisor of CSU
	Determination the job profile of each member of the CSU and if necessary reinforce the team	Workstation sheets was done
	Clearly definition of the tasks (who do what?) Through a very detailed organization chart.	Staff distribution and organization chart displayed
	Improvement of communication (verbal and written) between and within departments: each material entering or leaving the sterilization unit must be noted (when, by whom and state?) and the transmission of procurement instructions or handover must be written.	Presence reception and delivery notes for MDs Presence teams handover records
Operating Rooms	Reminding note to remove the batteries from microair motors before pre disinfection	Reminding note displayed (Annex 4)
	Training and awareness of operating rooms staff on the importance of the pre-disinfection control.	Sensitization was made by the supervisor of CSU
	Posting of pre-disinfection procedures and information supports in both operating rooms and central sterilization unit	MDs Pre-disinfection Procedure updated and displayed
	Equipment Repair of orthopedic operating room	Micro air motor repaired after four months
	Improvement of communication (verbal and written) between and within departments.	Presence teams handover records

registered by AEs reporting system in Sahloul University Hospital during three years (June 2018 to June 2021) and to analyze a case of AEs related to treatment of MDs according to ALARM Method. The ultimate aim of reporting AEs was to lead to systems improvements by understanding the systems failures.

In the present study, we notified only one unacceptable AEs related to treatment of DMs. It occurred during the pre-disinfection step where the battery of a micro air motor battery was not removed. These AEs was related to insufficient control before steam sterilization. In Sahloul University Hospital, pre-disinfection of MDs was made in operating rooms.

In order to make this risk acceptable, this AE was analyzed and investigated with involved parties about the chain of events that led to this accident using ALARM method and finally corrective measures were put in place and systematic causes were reduced. This method was a powerful and common means of investigating and analyzing clinical incidents and drawing out the lessons for enhancing patient safety. It was designed to promote a greater climate of openness and to move away from finger pointing and punitive culture to error. The responsibility was collective and not individual charge. An error has occurred because all functional and organizational barriers, that usually work, have failed. So, formal training, practice and acceptance of this method were needed for it to be fully effective [10,11]. Monitoring and feedback of corrective actions would not only make it possible to verify its relevance and identify the residual risks to be monitored, but also to ensure the effectiveness of the actions in look at the goals [12].

Typically, AEs were result of a combination of contributing factors; rarely there is just one causal factor [13]. Personal factors (training), teams and organizational factors (intra and inter unit communication) and task factors were contributed to this AE.

All healthcare professionals involved in the treatment of MDs must take certification courses or continuing training in the treatment of MDs with periodic and regular assessment of their skills [14].

Pre-disinfection MDs shall be based on the manufacturer's instructions. Procedures must be established to ensure that pre disinfection of MDs and sterilization processes followed the principles of infection prevention as set out by the Centers of Disease Control and prevention (CDC) and the World Health Organization (WHO) or the country Ministry of Health (MH). Completed policies and procedures should be reviewed and approved by the Infection Prevention and Control Committee. They must be readily accessible to staff doing the reprocessing. Review of reprocessing policies and procedures must take place at least annually. Audits of the cleaning process should be done on a regular basis [14].

In addition, failures in communication within inter-professional healthcare teams were established causes of AEs. Different providers had to be trained for communication skills and safe information transfer, particularly at the time of handover. Imperfect training of inter-professional communication was the main threatening factors for patient safety issues. A study by Gawande considered that lack of effective communication among the personnel was responsible in 43% of AEs [13].

To our knowledge, this was the first study describing AEs related to treatment of MDs in Tunisian hospitals. The limitations of this study were mainly the underreporting of AEs and feedback. The notification of incidents must take place with the support of operating rooms personnel, who need to be trained and convinced of the advisability and effectiveness of using such a tool.

Various studies showed that the number of reports can be increased significantly by different approaches. Introduction of AEs reporting system, like ours, based on voluntary and non-punishment reporting, centralization of database, involvement of health professionals in the process of analysis of AEs was effective [15]. Also, a systematic feedback would improve reporting rates if hospital staff and management found the information useful and relevant [16].

Conclusion

A voluntary AEs reporting system had been implemented at Sahloul University Hospital since 2018. The objective of the present study was to analyze a case of AEs related to treatment of MDs according to ALARM Method.

Unacceptable risk was analyzed according to ALARM method: Personal factors (training), teams and organizational factors (intra and inter unit communication) and task factors were contributed to this AE.

Main corrective measures were related to the improvement of traceability (checklist, procedures...) and verbal and written

communication between and within departments.

Since 2018, the CSU has been concerned with the implementation of a quality approach within the hospital. In addition, following the reporting of AEs, many improvement actions were taken: An improvement in the organization of work with the development of workstation sheets, Concerning traceability, an update of the procedures for MDs treatment was made, traceability between operating rooms, departments and the CSU through reception and delivery notes for MDs, teams handover records of the central sterilization unit, concerning the packaging, verification with the pharmacy of the quality and dimensions of the packaging paper, reinforcement of controls during the packaging of boxes (double control) and regular verification of the quality of the heat seal.

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